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10/576,774	03/16/2007	Tetsuo Okada	056291-5278	6009

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WASHINGTON, DC 20004

EXAMINER
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RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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### **DETAILED ACTION**

This office action is in response to the amendment filed on November 2, 2010.

Claims 1-11 and 13-17 are pending in this application.

### **Election/Restrictions**

Claims 6-11 and 13-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 21, 2010. The restriction was, however, maintained for the reasons provided in the previous office action(s) and made final in the previous office action.

This application contains claims 6-11 and 13-17 drawn to an invention nonelected with traverse in the reply filed on April 21, 2010. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### **Specification**

It is acknowledged that applicant submitted drawings for Figures 1-8 that appear on pages 25-32 of the specification. Further, applicant amended the specification to contain the "Brief Description of the Drawings". However, the specification continues to contain pages 25-32 illustrating the Figures 1-8 which is improper content for specification. As these pages have been resubmitted as drawings, pages 25-32 must be deleted from specification. Appropriate instruction to amend the specification is required in response to this office action.

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**Withdrawn Rejections/Objections:**

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

**The following rejections are necessitated by the amendment:**

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 03/016317. The reference teaches a process for preparing calcium salt forms of statins, including rosuvastatin. See the examples of various statins, including rosuvastatin (see the disclosure on page 2 and Examples 7 and 8). The reference teaches a reaction scheme illustrating the process

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to prepare a calcium salt of a statin on page 18, wherein the starting acetonide compound is reacted with an acid to form the corresponding diol-ester which is then converted to the calcium salt form. The reference teaches the hydrolysis of the ester group prior to the conversion to form the corresponding calcium salt. The instant claims recite that R is a (2-6C)alkyl as compared to the specific examples in the reference which teach 1C alkyl (i.e., methyl ester). The reference, however, generically teaches statin ester derivatives wherein R<sub>1</sub> is a C<sub>1</sub> to C<sub>8</sub> alkyl group (see page 9 or 13) and further, specifically teaches an ester derivative containing a C<sub>4</sub> alkyl group (i.e., tert-butyl ester, see page 18). One having ordinary skill in the art would have been motivated to use the reference process to prepare the calcium salt of rosuvastatin going through an intermediate of an (2-6C)alkyl ester derivative. One skilled in the art would have had the reasonable expectation of obtaining a product consistent with the teachings of the reference. The reference inherently teaches the step of obtaining a crystalline form of the intermediate compound, see for example, the teaching in page 12 lines 23-25. Accordingly, one of ordinary skill in the art would have had the reasonable expectation of having a crystalline form of the intermediate compound diol-ester derivative in the reference process.

Receipt is acknowledged of the Information Disclosure Statement filed on November 16, 2010 and a copy is enclosed herewith.

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**/Deepak Rao/  
Primary Examiner  
Art Unit 1624**

January 18, 2011